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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,009	01/25/2001	Steven P. Holzberg	00801.0172.00US00	6352

7590

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EXAMINER

HELMER, GEORGIA L

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/771,009

Applicant(s)

HOLZBERG ET AL.

Examiner

Georgia L. Helmer

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 31-57 and 59-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-30 and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Restriction election***

1. The Office acknowledges the receipt of Applicant's restriction election, Paper No. 10, filed 9 December 2002. Applicant elects Group I, claims 1-30 and 58 as drawn to SEQ ID NO: 1, without traverse. Claims 1-67 are pending. Claims 31-57 and 59-67, drawn to nonelected inventions, are withdrawn. Claims 1-30 and 58 are examined in this Office Action.

This restriction is made Final.

***Information Disclosure Statement***

2. A signed copy of Applicant's IDS form 1449, Paper No. 4 filed 21 May 2001, is included.

***Claim Rejections - 35 USC § 101***

3. Claims 1-14, 17, 19, 21-23, 28-30 and 58 are rejected under 35 U.S.C. 101 because 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-14, 17, 19, 21-23, 28-30 and 58 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims read on foot and mouth disease virus, a product of nature, which is non-statutory subject matter.

***Claim Rejections - 35 USC § 112-second***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7, 10, 13, 14, 17 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, "a 2A autoproteolytic peptide" is a shorthand name and does not tell what the peptide is or where it comes from. The metes and bounds of this claim are not defined.

In claim 10, the viral protein "gamma-b" is a shorthand name and does not tell what the protein is or where it comes from. The metes and bounds of this claim are not defined.

In claim 13, the viral protein "beta-b" is a shorthand name and does not tell what the protein is or where it comes from. The metes and bounds of this claim are not defined.

In claim 58, "the protein" lacks antecedent basis.

Clarification and/or correction are required.

**Claim Rejections - 35 USC § 112, first paragraph**

*Written description*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 7, 10, 13, 14, and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 is drawn to a polynucleotide of claim 1, where the autoproteolytic peptide comprises a "2A autoproteolytic peptide". There is no structural description, of what comprises a "2A autoproteolytic peptide, and there is no functional requirement or description. Applicants are claiming a genus of sequences, yet there is no description of the structural features or the functional features that define the genus.

Claim 10 and 13 are drawn to a polynucleotide of Claim 1, where the viral protein is "gamma b" or "beta b", respectively. There is no structural description, of what comprises gamma b" or "beta b", and there is no functional requirement, source, or description. Applicants are claiming a genus of sequences, yet there is no description of the structural features or the functional features that define the genus.

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See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . . Accordingly, the specification does not provide a written description of the invention . . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed. (see Written Description Requirement published in Federal Register/Vol.66, No. 4/ Friday, January 5, 2001/Notices; p. 1099-1111.)

### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, 7, and 11 rejected under 35 U.S.C. 102(b) as being anticipated by Donnelly, et al, (Journal of General Virology, vol 78, pages 13-21, 1997) Applicant's IDS.

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Donnelly teaches a polynucleotide encoding a promoter (p 15-16, Figure 2, see PTG 393, in plasmid constructs) operatively linked to a transcriptional unit, wherein the transcription units encodes a fusion protein, wherein the fusion protein comprises (1) a viral protein, (2) a protein of interest, and (3) an autoproteolytic peptide, wherein (3) is fused between (1) and (2), (p 15-16, Figure 2, see PTG 393, in plasmid constructs).

Donnelly also teaches a viral protein from an RNA virus, and an autoproteolytic peptide comprising a 2A autoproteolytic peptide (p 16, Figure 2 legend).

Accordingly, Donnelly anticipates the claimed invention.

### ***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 1-4, 7, 9-12, 15, 16, 19, 20, and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donnelly as applied to Claims 1, 2, 7, and 11 above, and further in view of Choi, et al, Plant Journal, 2000, 23, 547-555 (See IDS).

Donnelly does not teach plant viruses and monocot plants.

Choi teaches a single-stranded plant RNA virus (p 548, column 2), where the virus is capable of systemic expression (p 548, column 2), a plant cell infected with the recombinant virus (p552, Figure 4 and Table 6), and monocot plant cells and plants expressing foreign genes from this virus (p552, Figure 4 and Table 6).

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One skilled in the art would have been motivated at the time of the invention to substitute for the FMDV of Donnelly the virus of Choi with a reasonable expectation of success. Motivation for this was the knowledge that RNA plant viruses could express foreign genes in monocots but that these viruses did not spread systemically, and that such systemic movement and expression of the virus and foreign genes was desirable, as taught by Choi (p 547, column 1).

The use of two viral proteins, use of N-terminal and C-terminal fusion proteins and the relative orientation of the autoproteolytic peptide, a plant structural protein and a plant cell infected with the recombinant virus are obvious variants and reflect design choices, which were well within the knowledge and skill of one of ordinary skill in the art and could be used with reasonable expectation of success. Thus the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time it was made. Accordingly, the claimed invention is prima facie obvious in view of the prior art.

### ***Remarks***

12. No claim is allowed.
13. SEQ ID NO: 1 is known in the prior art.



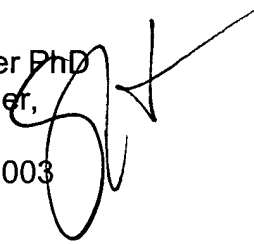
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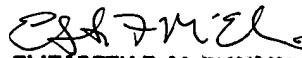
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia Helmer PhD  
Patent Examiner,  
Art Unit 1638  
February 24, 2003



  
**ELIZABETH F. McELWAIN**  
**PRIMARY EXAMINER**  
**GROUP 1800**